

REMARKS

I. INTRODUCTION

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

Claims 48, 101, 104, 106, 107, 109 and 111-113 are pending in this application.

II. THE OFFICE ACTION

The Examiner has maintained the rejection of claims 48, 101, 104, 106, 107, 109 and 111-113 over Sonnino in view of Khau. Applicant respectfully traverses.

At the outset, the Examiner has failed to establish a proper *prima facie* case of obviousness. Rather, the Examiner concludes, even in light of contradictory evidence of record, in the form of journal articles establishing the level of knowledge of one skilled in the art, that the present claimed invention is *prima facie* obvious over the teachings of Sonnino and Khau et al.

For a proper *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. See MPEP 2142.

The first criteria requires that there is some motivation or suggestion to modify the references or combine the teachings either in the references themselves or within the general knowledge of one skilled in the art. Substituting the sPLA2 inhibitor of Khau for the inhibitor of Sonnino appears to be based on a generalization that if IL-10 can be used for treating ischemia reperfusion injury in heart, liver, kidney, small intestine and pancreas then the sPLA2 inhibitors of Khau could be used to treating ischemia reperfusion injury in the

same tissues. In other words, the Examiner asserted that non-IL-10 compounds share the same properties as IL-10. No where does Moldawer teach or suggest, or is there any evidence of record which teach that all compounds have the same activity as IL-10. In fact, Moldawer itself doubts the credibility of the Examiner's assertion where Moldawer describes the prior art which states, at col. 1, lines 37-39, "[h]owever, there is no evidence in this publication that the non-IL-10 proteins would actually work for treating all of the disease in the long list." At the most, one skilled in the art would expect that substitution of a compound of Khau for the sPLA2 inhibitor of Sonnino would be effective for treating ischemia reperfusion injury in the intestine (Sonnino is limited to treatment of ischemia reperfusion injury in the intestine), however, there is no suggestion or motivation for expanding the substitution for effective treatment of ischemia reperfusion injury in the heart, liver, pancreas or kidney, as is recited in the present claims.

The second criteria requires that there is a reasonable expectation of success. In the present rejection, one skilled in the art would understand the differences between ischemia reperfusion injury in intestinal tissue and ischemia reperfusion injury in heart, liver, pancreas or kidney as shown by the journal articles which disclose that different levels of sPLA2 are present in intestinal tissue as compared to heart, liver, pancreas and kidney. Furthermore, the articles show that other factors contribute to ischemia reperfusion injury in heart, lever, pancreas and kidney. Because there is a clear involvement of other factors in treating ischemia reperfusion injury in heart, liver, pancreas and kidney and Sonnino is limited to treatment of ischemia reperfusion injury in the intestine, the combination of references fails to establish a reasonable expectation of success in treating ischemia reperfusion injury in heart, liver, pancreas or kidney as is recited in the present claims.

The final criteria for a proper case of prima facie obviousness is that the cited reference must teach all of the claim limitations. In the present claims, the ischemia reperfusion injury is located in heart, liver, pancreas or kidney. Neither Khau nor Sonnino teach treatment of ischemia reperfusion injury in heart, liver, pancreas or kidney. Rather, Sonnino is limited to treatment of ischemia reperfusion injury in intestine. Khau fails to teach or suggest any of the target tissues recited in the claims. The Examiner relies on Moldawer to show that IL-10 can be used to treat ischemia reperfusion injury in a variety of tissues. While

it is true that Moldawer discloses treatment of ischemia reperfusion injury in thoracic, liver, kidney, small intestine and pancreas, Moldawer discloses causes of ischemia reperfusion injury and suggests that they are related, at least in part, to excess amounts of proinflammatory cytokines, such as TNF- α , IL-1, IL-6, and IL-8 (col. 5, lines 41-44). Therefore, Moldawer fails to remedy the deficiencies of Khau and Sonnino in the final criteria for a proper prima facie case of obviousness which requires that the cited references teach all the claim limitations.

Rather, Moldawer appears to support Applicant's position that different factors are involved in ischemia reperfusion injury in organs such as heart, liver, pancreas and kidney and as such, one skilled in the art would not use the compounds of Khau for treating ischemia reperfusion injury in heart, liver, pancreas and kidney, with a reasonable expectation of success.

Based on the above analysis of the criteria required for a proper case of prima facie obviousness, the Examiner has failed to establish a proper rejection based on 35 U.S.C. § 103. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

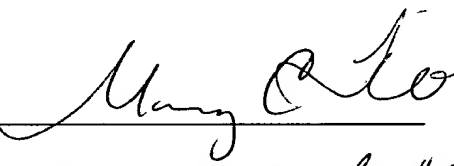
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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